FEDERAL REGULATION OF THE HEALTH CARE DELIVERY SYSTEM: A FOREWORD IN THE NATURE OF A "PACKAGE INSERT"

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As a remedy for problems of public policy, regulation is overprescribed. Indeed, regulatory programs are to many legislators what prescription drugs are to some doctors: a useful tool which it is tempting to overuse in an effort to demonstrate to the "consumer" (voter or patient, as the case may be) that the decision-maker cares and is trying to do something about the problem. One hopes in both cases that professional integrity supplies a check on overprescribing tendencies and that little harm is done when misuse occurs. But experience shows that legislators have often yielded to the temptation to regulate when other measures were preferable and that regulation frequently has severe side effects. Not the least of the problems is the accumulating evidence that regulation is habit-forming and, once prescribed, is practically impossible to discontinue. Indeed, small doses lead to ever-larger ones.

Numerous regulatory prescriptions have been written for the ailments of the health care industry, and many of them have been filled without careful consideration of the proper dosage level and mode of administration or the possible desirability of alternative therapies. A proper appraisal of pending proposals and of measures to implement new programs requires recognition that regulation has often proved neither efficacious nor safe as a remedy for the ills of the body politic. In the absence of an analogue of the Food and Drug Administration to examine the safety and efficacy of the products of our legislatures, authoritative evaluations of regulatory nostrums must be made in the political arena or in the newly created regulatory bodies themselves. Although political and administrative judgments are not usually grounded in scientific analysis, an

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available warning—in the nature of a "package insert"—about the side effects of regulation and the indications for its use may help conscientious public officials to avoid administering excessive measures of regulation in this case.

The Choices Ahead

The policy options in health care probably no longer include (if they ever did) the possibility of not regulating the health sector at all or of placing primary reliance on market forces. As this Symposium shows, the regulatory takeover is well under way, and powerful arguments warranting the movement in this general direction can be, and are, advanced. Nevertheless, many outstanding issues remain to be resolved concerning the scope, locus, and character of regulation and the totality of the displacement of private decision making. These issues arise continually in the drafting of new legislation, in the implementation of newly enacted laws, and in the making of regulatory decisions themselves. Their overriding importance will be more readily recognized and they will be more intelligently addressed if the traps into which other regulatory endeavors have fallen are known and borne in mind when analogous hazards are encountered. This Foreword attempts to set forth regulation's potential shortcomings in a context which will allow the health care sector to profit from the lessons concerning regulation which in recent months have become topics for discussion not merely among carping academics but also in policy-making circles at the highest level.

As one who has for some time decried the regulatory wolf at the health sector's door,2 I take some comfort that sophistication about the limitations of regulatory measures has grown in the health care sector in recent years. Indeed, although regulation is still seen, un-

1. "[M]uch useful information on such factors as indications, contraindications, dosages, toxicity, and side effects is included in the so-called package inserts which must be enclosed with each container of drugs." Task Force on Prescription Drugs, Final Report 23 (U.S. Dep't of Health, Education and Welfare, 1969).

derstandably perhaps, as the only solution worth considering, some halting but heartening steps have been taken toward tailoring regulatory institutions and sharpening regulatory mandates to avoid many of the worst pitfalls about which I and others have warned. While these measures may be inadequate and many hazards still remain as new regulatory interventions are considered and as recent legislation is implemented, perhaps the general warnings contained herein can assist in somewhat strengthening the odds that the public interest will be materially furthered by regulation of the health sector and that the goal of good-quality health care at reasonable cost will be attained. The footnotes in the ensuing general discussion of chronic regulatory malfunctions highlight health sector developments which either promise some relief from the baneful influences warned of or reveal analogous difficulties not yet overcome.³

**Regulation’s Genesis**

Since the Progressive Era, it has been customary to think of regulatory legislation as a vindication of the public interest over private greed, and the persistence of this view in the electorate has allowed legislators to produce, without fear of voter reprisal, regulatory laws which did not achieve such a vindication in fact or which had side effects worse than the disease. In recent months, however, an awakening of recognition of the frequently inflationary and pro-producer impact of regulation has suddenly occurred in our national political life. This dawning sophistication, stimulated by the work not only of economists emanating from the University of Chicago but also of such liberal heroes as Ralph Nader and his allies, opens for consideration the possibility that regulation’s failures are not merely occasional aberrations from the postulated public-interest objective—which might be correctable by better appointments, more participation by consumer interests, and bigger budgets for the

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³ The footnotes do not, however, document either the generalizations about or the specific illustrations of regulatory experience in fields other than health. On these matters, see generally Havighurst, *Certificate of Need*, supra note 2, at 1178-1215, and references cited therein; Frech, *Regulatory Reform: The Case of the Medical Care Industry* (unpublished paper prepared for the Conference on Regulatory Reform, American Enterprise Institute for Public Policy Research, Sept. 10-11, 1975).
agencies—but are in fact the norm. Moreover, there is a nagging suspicion that the disappointing results are not wholly out of keeping with legislative expectations. Nader and his colleague, Mark Green, have written that “our general industrial policy should encourage competition in our economy by minimizing regulation, except where clearly necessary”; although reasonable minds can differ on when regulation is “clearly necessary,” the state presumption against regulation seems warranted by many revealed abuses of legislative discretion.

It has been more and more widely observed that consumers are at a vast disadvantage in aggregating and obtaining appropriate attention to their numerous small interests in particular legislative matters. Industry trade associations, on the other hand, are keenly aware of where their interests lie and know how to manipulate the political system to assure that they are not adversely affected even when the public succeeds in raising an issue concerning industry performance. This pro-producer bias inherent in the political marketplace and evidence of frequent, even systematic, sacrifice of the public interest have seemed to some to support a revisionist hypothesis about regulation’s genesis—namely, that regulatory laws are either actually intended to benefit the regulated industry or, at best, are designed to pacify a clamorous public without doing net harm to the affected private interests. Although this hypothesis surely goes too far, the underlying point about the legislative process is well taken and has relevance to health legislation. The increased political sophistication and lobbying effectiveness of health sector interest groups are now formidable factors in the legis-


6. Although consumer interests in health care appear well represented in the legislative process, it is not clear that taxpayer and premium-payer interests are adequately protected, against provider and consumer lobbying for more and better services and programs, some of which may not be worth their cost. See Havighurst & Blumstein, supra note 2, at 15-30. Government’s own proprietary interest as a major purchaser seems to provide the chief impetus for control of health care costs, but these efforts, largely confined to federal programs, may harm the needy but be of little value to middle-class victims of third-party-payment-induced inflation.
ative process, influencing the shape and substance of every regulatory measure affecting health care.\(^7\)

*Regulation’s Political Environment*

The politics of administering a regulatory scheme, once it is enacted, are also discouraging as to the likelihood that the public interest is kept paramount. Once again, the regulated interests are best able to gain the ear of the agency and of the political figures who influence its budgets and legislative charter. While industry influence over the regulators is often described as reflecting the “capture” of the agency, this characterization suggests more of a conspiracy than may in fact be involved. Quite simply, the comparative advantage of the regulated industry in making the regulator’s life more difficult leads to systematic favoritism, designed to discourage appeals either to the courts\(^8\) or to the agency’s political overseers.\(^9\)

Because they operate in a political setting, regulatory agencies are naturally given to seeking compromise, and this propensity results in giving recognition to interests in proportion to their “clout” rather than in proportion to their merit. As the agencies perceive their task as primarily one of mediating among interest

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7. The hospital industry has developed and supported numerous proposals for its own regulation. Organized medicine has benefited substantially from health legislation, particularly medical licensure and financing programs, without as yet accepting substantial controls.


9. Organized medicine’s dedication to influencing administration of the PSRO program is reflected in this declaration by the director of the AMA’s Center for Health Services Research and Development:

> It seems apparent after examining the legislation that the primary, if not total intent of the program is to contain the cost of medical care.

> Despite the legislative intent of the program, however, the concern of health care providers and insurers should be to reassign priorities of the PSRO program to assure that maintenance of high quality care is the primary focus of PSRO’s.

groups, they shrink from the harder task of defining the public interest objectively and compelling the affected interests to abide by their definition. As Theodore Lowi has said, interest-group liberalism "replaces planning with bargaining." Experience with so-called "health planning" confirms the fear that such planning involves political mediation and compromise more than planning of the technocratic variety. The regulatory framework currently being erected on the foundation of health planning is therefore likely to disappoint any hopes that the defects of the political model could be escaped in regulating the health care industry. It is not clear whether the recent National Health Planning and Resources Development Act was primarily intended to endorse reliance on and improve the working of the political model or to weaken the political character of the process and strengthen the emphasis on "hard" planning.

Even where regulation necessarily imposes some hardship, the agencies usually feel constrained to provide offsetting benefits to their regulated constituents. For example, the Civil Aeronautics Board (CAB) is well known for its evenhandedness in distributing the burdens of regulation as equitably as possible among the airlines, helping the weaker, less efficient ones while protecting all of them against the appearance of new trunkline carriers and main-

11. See Havighurst, Certificate of Need, supra note 2, at 1194-1204.
13. This legislation sharply focused attention on the desirability of political "accountability" of the local health systems (planning) agencies (HSAs) to be created. A proposal to require all HSAs to be private nonprofit corporations, insulated from local politics, was defeated by a combination of providers and elected officials, and implementation of the law as enacted has also reflected pressures for politicizing these agencies. See Iglehart, Health Report: States, Cities Seek Role Over Regional Planning Bodies, 7 Nat'l J. Rep. 1207 (1975). Even though the act takes great pains to structure the HSA governing boards democratically, it may fail to achieve adequate representation of the interest in cost control (see note 6 supra) and perhaps other interests as well.
14. The law provides substantial funding for HSAs, a strong mandate for planning, backup technical resources, and perhaps enough independence from political pressures (see note 13 supra) to warrant expectations that objective definitions of needs will be adopted and adhered to. But cf. Havighurst, Certificate of Need, supra note 2, at 1194-1204. Moreover, a technically competent and credible HSA might well provide an important check on the discretion of the state agency charged with formal decision-making authority.
taining fares at high levels. The privileges and revenues which regulation generates are not openly appreciated, of course, but recent moves to deregulate the airlines and truck transport have revealed the identity of interests between the regulators and the regulated. A typical headline reads, “Carrier support for status quo helps ICC resist pressure for major overhaul.” In all regulated industries, an appearance of antagonistic interests may conceal the deeper truth.

Exercise in Futility?

On those occasions when regulators pursue their view of the public interest with unusual vigor, they may still find that it is beyond their power to make much of a difference. Due to bargains struck in the process of enactment, their statutory powers may be insufficient to accomplish major changes, and the burdens of day-to-day administration may prevent attention to long-range planning and implementation of aggressive policies. Examples of how agency energy may be absorbed in trivial activities are provided by the Federal Communications Commission (FCC) and the CAB, which have caused the expenditure of vast resources—not only agency funds but private resources as well—in deciding which of several qualified applicants will be allowed to provide a lucrative service; this is a matter in which the public has no significant stake. Similarly, “regulatory lag,” occasioned by complexity and

15. 5 Nat’l J. Reports 103 (1973).

16. For example, physician dislike for the PSRO program should not obscure the numerous ways in which PSROs may protect physician interests. See generally Havighurst & Blumstein, supra note 2, at 41-51, discussing how the regulators “sold” the PSRO program to organized medicine by downplaying its burdens and emphasizing its benefits.

17. Regulation to deal with the excess supply of hospital beds and services has taken the form of limiting new entry but has not provided for eliminating existing but unneeded facilities. But see § 1513(g)(1) of the Public Health Service Act, as amended by P.L. 93-641 (codified as amended at 42 U.S.C.A. § 300I-2 (Supp. I, 1975)); H.R. Rep. No. 93-1382, 93d Cong., 2d Sess. 65 (1975).

18. The experience with health planning may be attributable to such burdens and resource limitations. See notes 11-14 supra and accompanying text.

19. Regulation of entry into the nursing home industry on the basis of need (as opposed to competence and integrity) may also be a wasteful regulatory activity, diverting attention from more important business. See Havighurst, Certificate of Need, supra note 2, at 1167-69.
the demands of due process, may prevent the regulators from dealing effectively with issues of current importance.

The practical impossibility of controlling all of the inputs and outputs of the regulated firm may also cause regulatory efforts to be unavailing. Thus, it is often possible for the regulated firm to allow the quality of its service to deteriorate in subtle ways as a means of increasing profits while under a regulatory constraint. Introducing rate regulation in the health care sector might well produce such quality sacrifices or other evasive action. Not only would quality variations be much more difficult to identify and regulate here than in public utilities, but residual competition among providers cannot be relied upon to maintain it—as it does in the airline industry, for example.

Professor George Stigler and Claire Friedland, noting that regulators are obviously very busy, remind us that "the innumerable regulatory actions are conclusive proof, not of effective regulation, but of the desire to regulate." The health care system has yet to have the benefit of convincing research which demonstrates that economic regulation of its components does more than "slightly heckle the state of affairs," as Stigler and Friedland put it, without improving them significantly. It is of course even more difficult to show that regulation produces better results than alternative measures designed to strengthen market forces and remove artificial restraints.


21. Because the content of medical services can be varied in subtle ways, fee schedules can be circumvented by increasing the number of services rendered and billed. Experience under the Economic Stabilization Program suggested that charge levels were better controlled than total provider income.


23. Id. at 2.

24. Strict capital investment controls in New York from 1964 to 1971 appeared to slow investment and raise occupancy rates substantially, but overall health care cost trends were not visibly affected. Quite possibly, regulation merely changed the input mix, perhaps increasing the labor component. Thus, "inflationary pressures may, like a balloon, bulge out at another place if growth in one direction is effectively prevented." Havighurst, Certificate of Need, supra note 2, at 1148. See also id. at 1217-20; Salkever & Bice, The Impact of Certificate-of-Need Controls on Hospital Investment (unpublished manuscript, Aug. 1975).
Ineffectiveness is not the worst hazard by any means, since regulation can cause substantial affirmative harms which will be so hidden from public view as to make their amelioration unlikely. Because of their political environment, regulators will usually attach higher priority to apparent harms than to those which are not visible to the public eye. Indeed, given the nature of politics, it is quite possible that a regulatory program would be designed to eliminate visible costs by substituting hidden ones. There is no guarantee that these new costs would not be larger than the visible costs which prompted the intervention.25

Not all of regulation's costs will be hidden, of course, and yet their rectification may still be hard to bring about. The CAB's impact on airline fares is amply revealed by the performance of California's unregulated intrastate airlines, whose fares have been about two-thirds the level of charges for comparable CAB-regulated service. Yet nothing changed for many years after this evidence became available, and there is still doubt that anything substantial will occur as a result of recent interest in the problem. Similarly, the costs of the Interstate Commerce Commission's (ICC) performance in setting the conditions for the allocation of freight shipments among competing railroads, trucks, and barges, which is predicated mainly on a desire to minimize harm to the various carriers, have been responsibly estimated in the billions of dollars per year. But this huge cost is so widely distributed in the prices we pay for the various products shipped by inefficient modes or at excessive prices that no single constituency has much occasion to protest.26

25. A much debated study, Peltzman, *The Benefits and Costs of New Drug Regulation*, in *Regulating New Drugs* 112 (R. Landau ed. 1973), purports to prove that a large net welfare loss has been incurred as a result of regulatory legislation restricting pharmaceutical innovation. Peltzman's study marshals much persuasive evidence that, but for regulation, many valuable drugs would have been invented. But his failure to convince his critics, attributable to the impossibility of showing conclusively what would have happened under circumstances which were not allowed to occur, is useful as a demonstration that the costs of regulation may be as undiscoverable as they are real. Perhaps all Peltzman has proved is that one thalidomide incident is worth a thousand econometric studies.

26. Once the nation adjusts itself to paying for unnecessary health care, so that the expense is embedded as a relatively stable item in governmental and household budgets, the political world's interest in health care costs will have disappeared. This will be true even if the nation is spending twice as much on
Simple inefficiency—less output per unit input—is another insidious threat from regulation. Not only is inefficiency invited by the "cost-plus" character of most rate controls, but it is almost perfectly hidden from public or regulatory attention. Nevertheless, since much of the health world now operates on a cost-reimbursement arrangement with third-party payers, prospective rate regulation seems to promise some real improvement. Even so, regulators will see themselves as ultimately responsible for the industry's financial health, and cost-related increases will therefore be tolerated while incentives to achieve cost reductions remain weak.

Enemies of Change

Perhaps the most destructive regulatory inclination is the one which leads to protection of regulated interests against outside competition. Usually the regulators see themselves as defenders of an existing "system" which must be maintained in the public interest against all seemingly subversive influences. Thus, the ICC sought new legislation to protect the railroads against the incursions of trucks and barges, and cable television has been restrained by the FCC in order that the "quality" of over-the-air broadcasting not suffer. The examples could be multiplied.

One can anticipate that regulators of the health care system would adopt similarly restrictive policies toward such competitive innovations as health maintenance organizations, surgicenters,

health care as is socially optimal, meaning that half the outlay goes for things not in any relevant sense worth their cost. See Havighurst & Blumstein, supra note 2, at 60-61.

27. Rate regulation has been embraced by hospitals in large measure to legitimize their charges, thereby strengthening their hand against the major third-party payers, Blue Cross and Medicare. See, e.g., McCleary, Maryland: Proving Ground for Regulated Hospital Rates, PRISM, May 1975, at 24.

28. Concerns about "cream-skimming" are at least as great in the hospital world as in other regulated industries. See text accompanying note 35 infra; Havighurst, Certificate of Need, supra note 2, at 1164-65, 1188-94.

29. HMOs might well be discriminated against in entry regulation, at least after one such innovative delivery organization was established in the community. See note 31 infra and accompanying text; Havighurst, Certificate of Need, supra note 2, at 1207-15. But an even more serious problem confronting the HMO is its subject to regulation by PSROs, entities certain to be dominated by the HMO's arch-enemies and competitors, fee-for-services physicians. Even without overt oppression, PSROs are unlikely to appreciate HMOs' cost-saving innovations or the value of their unique approach to care. See generally Havighurst & Bovbjerg,
abortion clinics, proprietary hospitals, and other new developments which might substitute cheaper for more expensive (e.g., outpatient for inpatient) care. 30 Even though professing support for change in the health care system, the health planners and would-be regulators would allow innovative delivery systems to enter the market only on limited terms, allowing a dash of innocuous "pluralism" but prohibiting anything competitive enough to threaten the stability or perquisites of the existing system. 31 The cost of such regulatory discouragement of change would appear merely in a continuing high level of expenditures for health care, and it would be difficult to prove the actual extent to which regulation had made consumers worse off. 32 Both the regulators and existing providers, including the newly admitted innovative modes, would favor continuation of regulatory protectionism.

A Swollen Health Sector

Another fault to which regulators must plead guilty is the encouragement of excessive investment of society's resources in the regulated activity. Maintenance of very high quality standards, higher than an informed public would insist upon if given its choice between slightly higher quality and significantly lower price, is one way in which this could occur. 33 The risk of unwarranted growth

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30. See Havighurst, Certificate of Need, supra note 2, at 1207-15. Restrictive legislation affecting such providers has been adopted in many states.

31. The regulatory provisions of the Health Maintenance Organization Act of 1973, P.L. 93-222, 87 Stat. 914 (codified at 42 U.S.C. § 300e et seq. (1974)) resulted from the concurrence of organized medicine and Congressional liberals on the desirability of imposing substantial controls and expectations on HMOs. Because HMOs found it nearly impossible to function under the act, amendments are now being considered. Iglehart, Health Report/HMO Act Changes Advanced to Bolster Troubled Program, 7 Nat'l J. Rep. 1161 (1975). The HMO legislation illustrates one way in which regulatory legislation can serve the needs of established interests in curbing competitive developments. It is noteworthy that § 2 of P.L. 93-641 endorses the fostering of lower-cost substitutes for inpatient care and that other sections also favor HMO development; but these sentiments may not much affect the substance of decisions.

32. Hospital utilization under Blue Cross plans is lowest in West Coast states, where HMOs are most firmly established. It is arguable that this reflects HMOs' competitive impact on fee-for-service practice and provides a measure of the cost of retarding HMO development.

33. The HMO Act illustrates this problem. By mandating a more compre-
associated with "excessive" quality seems particularly great in the health sector since the regulators of quality will have either (1) no explicit responsibility for the cost of care or (2) no courage to face the criticism that they have settled for less than the highest standard of quality. The ICC's attempted fostering at great expense of a "dependable" system of common carriage and the allegation that the Bell System's regulated monopoly is "gold-plated" reveal the hazard that the trade-off between the quality and cost of service will frequently be ignored under regulation and that more and better services will be the prevailing watchword.

Another factor contributing to excessive industry size is the imposition by regulators of requirements that certain services be rendered even though they cannot pay their own way. For example, before Amtrak, the ICC forced railroads to continue passenger services even when very few travelers wanted to ride the train; the FCC insists on unremunerative "public-interest" programs which few watch; transportation and freight rates are kept below cost for certain industries and localities, and so forth. All these subsidized services must be supported by funds generated by the regulated firms in other ways, and this means that monopoly prices must be set on those services which are in substantial demand. Thus, although regulation is thought of as prohibiting monopolistic pricing, it often turns out to encourage it and even to protect it against competition which would erode it. Professor George Hilton describes regulatory commissions as having a tendency "to generate monopoly gain in one activity, either through administering a cartel or maintaining a monopoly, and then to dissipate it in uneconomic activity."35

hensive benefit package than consumers were willing to pay for, Congress put HMOs at an impossible disadvantage. It is notable that some national health insurance proposals would mandate similar benefit packages for everyone, compelling people to finance collectively what they are unwilling, even with major tax inducements, to purchase individually. See note 26 supra. Legislative and regulatory judgments on matters of this kind are frequently wrong in assessing people's true wants. See generally M. Weidenbaum, Government-Mandated Price Increases: A Neglected Aspect of Inflation (1975).

34. See generally Havighurst & Blumstein, supra note 2.

35. Hilton, The Basic Behavior of Regulatory Commissions, 62 Am. Econ. Rev. 47, 50 (1972). It is reassuring that the Public Health Service Act, § 1533(d) as amended by P.L. 93-641 (codified as amended at 42 U.S.C.A. § 300n-2(d) (Supp. 1, 1975)), provides some indications that internal subsidies in health care institutions are to be identified and discouraged. See also Cohen, State Rate Regu-
It is, to say the least, curious that regulatory mechanisms which have encouraged other regulated industries to absorb excessive resources are being offered to correct inflation and excessive growth in the health care industry. The more reasonable expectation is that regulation will continue to foster more and better services and ever-higher quality. If the reader thinks this sounds good, he has missed the point—that health care can absorb too much of society’s resources and will do so if regulators of the health care sector behave as others have.

Warning!

The health care system and policymakers must be on their guard against prescribing more and more restrictive regulation as a sure cure for present ills. Overbroad though they may be, the generalizations offered here are designed to warn of side effects and contraindications and to assist in developing a proper regimen. Quite possibly, variations in the dose or the manner of administration can substantially ameliorate the dangers warned of, but more than vague assurances are needed. It may not be possible to correct the mistakes that are made or to affect regulatory behavior significantly through instructional statutory mandates.

Most of the problems attributable to regulation stem from the political system’s propensity to adopt palliative rather than curative measures, to treat apparent symptoms rather than underlying causes. Public policy formation, like much modern medicine, tends to be excessively crisis-oriented and to lack an adequate concern for health maintenance—that is, for the maintenance of healthy, self-regulating economic systems. Indeed, government seems to treat all problems as chronic ones and to neglect many opportunities for restoring the organism to health so that continuing intervention is not called for.

_36_ The current attention to amending the HMO Act, _supra_ note 31, is encouraging, though the amendments are likely to leave the law more restrictive of competition than is desirable. See _generally_ INSTITUTE OF MEDICINE, HMOs: _Toward a Fair Market Test_ (Natl Acad. of Sciences 1974).

_37_ The generally admirable listing of criteria for decision making in Public Health Service Act, § 1532(c), as amended by P.L. 93-641 (codified as _amended_ at 42 U.S.C.A. § 300a-1(c) (Supp. 1, 1975)), cannot be relied upon to control sub-
My own prescription has been, and still is, for an infusion of independent health maintenance organizations, requiring facilitative measures of various kinds but subsidies no greater than necessary to compensate for the artificial barriers which HMOs necessarily encounter.\textsuperscript{38} No doubt this competitive tonic would have to be supplemented by doses of regulation designed to relieve symptoms while it takes effect, to minimize possible side effects, and to steady the "invisible hand." But, once the limitations of more sweeping regulatory measures are properly appraised, this course of treatment offers the best hope for bringing the health care system through the present "crisis" and restoring to it some measure of functional independence.

\textsuperscript{38} See generally Institute of Medicine, supra note 36.